CERTIFICATE OF MAILING BY FIRST CLASS MAIL (37 CFR 1.8) Applicant(s):			Docket No. 24647-81051	
Application No. 09/762,152	Filing Date February 1, 2001	Examiner Haghighatian, Mina	Customer No. 34492	Group Art Unit 1616

Invention: METHOD AND APPARATUS FOR TREATMENT OF RESPIRATORY INFECTIONS BY NITRIC OXIDE

I hereby certify that this **DECLARATION OF DR. NEIL MACINTYRE, M.D., PURSUANT TO 37 C.F.R. 1.132**
(Identify type of correspondence)

is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on **October 15, 2004**.
(Date)

Melody K. Gutierrez
(Typed or Printed Name of Person Mailing Correspondence)

(Signature of Person Mailing Correspondence)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Chris C. Miller

Serial No.: 09/762,152

Filed: February 1, 2001

For: METHOD AND APPARATUS FOR TREATMENT OF RESPIRATORY INFECTIONS BY NITRIC OXIDE INHALATION

Group Art Unit: 1616

Examiner: Haghighatian, Mina

DECLARATION OF DR. NEIL MACINTYRE, M.D., PURSUANT TO 37 C.F.R. § 1.132

Mail Stop Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

1. I, Dr. Neil MacIntyre, M.D., have been asked to provide this declaration in connection with the patent application captioned above, which relates to the use of inhaled nitric oxide gas as an anti-infective.

2. A copy of my curriculum vitae is attached as Exhibit 1 to this declaration. By way of summary, I am presently the Chief of Clinical Services in the Division of Pulmonary and Critical Care Medicine at the Duke University Medical Center. Since 1981, I have also served as the Medical Director of Respiratory Care Services, the Pulmonary Function Laboratory, and the Pulmonary Rehabilitation Program at Duke. I have served on the editorial boards of such journals as Respiratory Care, Critical Care Medicine, Health Devices, and the Journal of Cardiopulmonary Rehabilitation. I have also authored or co-authored many publications in the field of respiratory care, as

reflected in my CV. I am highly experienced in the use of therapeutic and ventilatory *gases* in respiratory care, and have written broadly in this field. In addition, as described in more detail below, I have written a number of articles specifically relating to the use of *aerosols* to deliver therapeutic compounds to the respiratory tract.

3. I have been asked as an expert in the fields of Respiratory Care and Pulmonary Diseases to review the patent application captioned above, and its claims, in the light of the prior art publication No. WO 95/09612 by S. Green et al ("Green"). I have also reviewed the Green reference, and the comments of the U.S. Patent Examiner as expressed in the USPTO Office Action mailed April 16, 2004. I find that I disagree with the USPTO examiner in rejecting the patent application claims based on Green, or based on the combination of Green and US Patent No. 5,558,083 by Bathe et al ("Bathe"). In summary, I do not believe that 1) Green disclosed a method of delivering nitric oxide gas by inhalation to kill or inhibit the proliferation of microorganisms in the respiratory tract or that 2) One ordinarily skilled in the art would have found it to be obvious to take the different approach disclosed by Green and change it so as to deliver inhaled nitric oxide gas directly by inhalation to kill or inhibit such microorganisms or to suppress a respiratory infection associated with the microorganisms. I base my comments on the following facts:

4. Throughout the Green reference, the authors describe the administration of nitric oxide "generators" or "releasing compounds" that are intended to generate or release nitric oxide. By definition, a nitric oxide releasing "compound" or "generator" implies the presence of at least two chemical entities compounded together that are required to produce the nitric oxide. Likewise, in all the examples given in the Green

reference, the nitric oxide generator that is administered is always in the form of some non-gaseous precursor compound – specifically a "nitric oxide/nucleophile" adduct that contains some material or molecular portion other than molecular nitric oxide – that is intended, eventually, to react or otherwise release nitric oxide in an aqueous solution. For example, at pages 15-20, Green describes that the nitric oxide/nucleophile adduct can be bound to a polymer material, and at pages 28-30 Green describes the use of liposomes to encapsulate the nitric oxide/nucleophile adduct. Table 1 of Green at page 27 lists the preferred nitric oxide/nucleophile adducts, all of which are themselves large molecules that cannot be administered in gaseous form. Nowhere does Green describe the direct inhaled delivery of nitric oxide gas in the pure molecular form, so as to result in exposure of nitric oxide to microorganisms within the respiratory tract.

5. In fact, the Green reference directly teaches away from the approach of delivering nitric oxide gas directly through inhalation for killing or inhibiting microorganisms in the respiratory tract. For example, the authors state that the use of a nitric oxide releasing compound in treating animals, particularly humans, "circumvents the disadvantage of the use of pure nitric oxide, aqueous solutions of nitric oxide, and compounds which release nitric oxide but require undesirable activation mechanisms" (page 21, line 33 to page 22, line 3). According to Green, the described nitric oxide releasing materials are "capable of specifically targeting the delivery of nitric oxide generating compounds, and of modulating the rate of generation of nitric oxide" (page 22, lines 3-7). These features that Green describes for these nitric oxide generating materials are not characteristics of inhaled nitric oxide gas.

6. In addition, Green states that, "Nitric oxide in its pure form, however, is a highly reactive gas having limited solubility in aqueous media (WHO Task Group on Environmental Health Criteria for Oxides of Nitrogen, Oxides of Nitrogen, Environmental Health Criteria 4 (World Health Organization: Geneva, 1977). Nitric oxide, therefore, is difficult to introduce reliably into most biological systems without premature decomposition" (page 4, lines 12-18). These statements indicate that inhalation of nitric oxide gas into the airway of a human would be an unreliable manner in which to deliver effective levels of nitric oxide into the liquid lining of the lungs or into the mucus, both of which could contain respiratory pathogens. Thus, one skilled in the art would have found no suggestion or motivation in the information disclosed by Green to deliver molecular nitric oxide in its gaseous form to treat infections, even though the methods of delivering inhaled nitric oxide gas had been disclosed in other contexts by others.

7. Green refers to quite a number of techniques for delivering the described nitric oxide releasing compounds, including polymer materials for use with implants or patches (page 15, linea 1-5), targeting with antibodies or site-specific peptides or oligonucleotides (page 16, lines 19-27), vesicle-encapsulated nitric oxide generators (page 20, lines 17-26), oral formulations (page 22, line 24 to page 23, line 6), injectable forms (page 23, lines 14-28), etc. None of these involve application, let alone inhalation, of nitric oxide gas. Rather, they all involve application of some compound or material that only indirectly releases or generates molecular nitric oxide.

8. As the Examiner has pointed out, Green also refers to administration of the nitric oxide releasing compound using "aerosol" formulations that include the

releasing compound (page 23, lines 7-13; page 29, lines 20-22). Once again, these "aerosol" formulations do not involve inhalation of gaseous nitric oxide, but rather only topical application, within the lungs, of some non-gaseous compound or material that only indirectly releases or generates molecular nitric oxide. Furthermore, the described use of aerosols to administer a non-gaseous active agent is fundamentally different from the claimed inhaled administration of gaseous nitric oxide.

9. In this regard, I have worked extensively in clinical applications with aerosol form therapeutic compositions, and have authored or co-authored a number of publications in this field. Examples of my work in the field of aerosols include the following:

1. Chairman, American Respiratory Care Foundation. Aerosol Consensus Conference, Cancun MX, 1990

2. Chairman, American Respiratory Care Foundation. Aerosol Consensus Conference II. Bermuda, 1999

3. MacIntyre NR, Silver RM, Miller CW, Schuler F, Coleman RE. Aerosol delivery in intubated, mechanically ventilated patients. Crit. Care Med. 1985; 13:81-84.

4. Weg JG and the Exosurf ARDS study group (NR MacIntyre, member). Safety and potential efficacy of an aerosolized surfactant in human sepsis induced ARDS. JAMA 1994; 272:1433-1438.

5. Anzvueto A and the Exosurf Acute Respiratory Distress Syndrome Sepsis Study Group (NR MacIntyre member). Aerosolized surfactant in adults with sepsis induced acute respiratory distress syndrome. New Eng J. Med. 1996; 334:1417-1421.

6. MacIntyre, NR. Aerosolized medications for altering lung surface active properties. Resp Care 2000; 45: 676-83.

7. MacIntyre, NR. Intratracheal catheters as drug delivery systems. Resp Care 2001; 46: 193-7.

8. MacIntyre NR. Aerosol delivery through an artificial airway. Respiratory Care. 2002; 47:1279-88.

9. MacIntyre, NR. Intra-tracheal aerosol delivery in intubated patients. in Vincent, JL (ed). Yearbook of Intensive Care and Emergency Medicine. Springer, Berlin, 2001.

10. Rinaldo S, MacIntyre NR. Continuous nebulization of albuterol sulfate for patients experiencing acute airway obstruction. Resp. Care 1992; 37:1370.

11. MacIntyre NR, Coleman RE, Schuller FS, Zaccardelli D, Pattishall E. Efficiency of the delivery of aerosolized artificial surfactant to intubated patients with ARDS. Am. Rev. Resp. Dis. 1994; 149:A125.

12. MacIntyre NR, Baran G, Schuller F, Day S. A small diameter multilumen catheter for intra - airway generation of therapeutic aerosols. Am. J. Resp. Crit. Care Med. 1996; 154:A.

13. MacIntyre NR, Baran GT, Schuller F, McConnell R. Aerosol deposition during high frequency oscillatory ventilation using an aerosol generating catheter. Eur. Resp. Soc. 1997;A.

10. One central point to understand about the aerosol administration of a non-gaseous compound as described by Green is that many pathogenic microorganisms respond to cytotoxic challenges by mutation into more resistant pathogens. Nitric oxide, because of its cytotoxic capabilities, has been shown to cause phenotype changes in some microorganisms due to nitrosative stress. This is of particular importance if the dose applied to the microorganisms is insufficient to eradicate them, as I believe would be expected to be the case if an aerosol, non-gaseous approach were used as described by Green.

11. As is well known to those skilled in the art of aerosol delivery, only a small fraction of aerosolized solutions actually get into the lungs. Even with the best techniques, standard aerosolization devices (nebulizers) with appropriate mouthpiece deliver only about 5.0-20.0% of their material into the lungs, and the remainder is wasted in the mouth or exhaled back out into the environment. Not only is the amount limited,

but the amount delivered varies considerably by the selection of the device used, so that the dose delivered to the site of the pathogens will also vary depending on the device selection, and on the particular skills of the patient in using that device.

12. Furthermore, aerosol delivery to the lungs has been frequently discussed in the literature, and it is well established that aerosol delivery does not achieve uniform deposition throughout the lungs. Not only is the uniformity of the deposition a function of the particle size produced by the aerosolization device, factors such as the physical characteristics of the material (hydroscopic properties, particle charge, viscosity, etc.), the speed of inhalation and the degree of airway disease will affect how much drug will get to any single location. Thus, short of a quantitative research study of each device and each patient, it would be difficult or impossible to determine how much of the active agent of a particular aerosol formulation is being delivered to the lungs, and to what part of the lungs.

13. With the aerosol approach described in Green, it is highly unlikely that an effective amount of the inhaled non-gaseous particles in the dose would actually make contact with the microorganism. I believe that there is a significant potential that the molecule will never reach more than 20 percent of the lung. The wide variation in concentration throughout the lung would mean that large sections of the lung would be overdosed while other sections would be under-treated and perhaps cause pathogen mutagenicity.

14. The approach by Miller in the present patent application offers significant advantages over that disclosed by Green. First, inhaled gases breathed continuously reach a steady state condition, usually within 3-7 minutes, whereby all surfaces of the

lungs that are in communication with the airways would be exposed to a uniform concentration of the drug. This would provide a uniform drug delivery to all locations and therefore expose all pathogens to the desired target nitric oxide dose.

15. Second, gas concentration selection can finely control the dose and duration of effect. Pure molecular nitric oxide gas diluted appropriately in air or in another ventilatory gas has an effect that lasts less than 6 seconds so that to change or stop the dose, it requires no other actions other than setting a different inspired concentration or ceasing delivery of the drug. This is not the situation with the aerosol methodology described by Green, where non-gaseous nitric oxide releasing particles would be deposited on relatively undefined portions of the lungs, where release of nitric oxide would then occur at some rate and potency that depends on the characteristics of the administered nitric oxide releasing formulation and the nature of the application site (page 24, line 21 to page 25, line 15).

16. Further in this regard, Green discloses a method of having the patient inhale a second "scavenger" compound to "counteract the inhibitory effect of the compound capable of releasing nitric oxide" (page 21, lines 17-26). To accomplish this, however, Green would need to know how much drug was delivered (as I previously stated, this would be unable to be determined by most means other than in a research facility) and then another drug would have to be delivered to the exact site of the original deposition to scavenge the nitric oxide produced by the generating compound. It would be difficult or impossible to assure that both the nitric oxide generating drug and the deactivating drug would have the same characteristics, or that the patient would inhale at the same speed or that the device for producing the aerosol would make both materials in

the same exact range of particle size. In contrast, because of the relatively instantaneous effects of inhaled gaseous nitric oxide, and the ability to cease (and resume) administration quickly and efficiently, the approach claimed in the present application does not suffer from the drawbacks of the non-gaseous aerosol approach of Green.

17. In conclusion, I believe that the use of inhaled gaseous nitric oxide as claimed in the present application is clearly superior to the non-gaseous, aerosol approach describe in the Green reference. In addition, I do not believe that person of ordinary skill in the art as of 1998 would have found it obvious to take what is disclosed by Green and, even with the knowledge of how to deliver pure molecular nitric oxide gas to the lungs (as described for example by Bathe), use inhaled nitric oxide gas to treat pulmonary infections. This statement stands particularly strong in light of the cautions against the use of nitric oxide gas presented by Green, which were unrelated to the ability to inhale nitric oxide gas but rather related to Green's view of the lack of potential effectiveness of the gaseous form of molecular NO.

18. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001

of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed.

Executed this 12 day of October, 2004, at Durham, NC, U.S.A.

Neil Ross MacIntyre, Jr., M.D.

CURRICULUM VITAE

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BIRTH DATE/PLACE: November 21, 1946, San Diego, California

FAMILY: Suzanne (wife), Catherine, Neil III, Douglas, Charles, Elizabeth, Stephen (children)

EDUCATION:

University of San Francisco San Francisco, California	Bachelor of Science 1968 (cum laude)
Cornell University Medical College New York, New York	Doctor of Medicine 1972

POST GRADUATE TRAINING:

Intern, Junior Resident, Senior Resident (Medicine)
Cornell University Medical Center - New York Hospital
New York, New York
1972-1975

Fellow (Pulmonary Diseases)
University of California, San Francisco
San Francisco, California
1978-1981

MEDICAL CENTER POSITIONS:

Medical Director of Respiratory Care Services, Pulmonary Function Laboratory, and Pulmonary Rehabilitation Program
Duke University Medical Center
1981-present

Interim Director of Respiratory Care Services
Duke University Medical Center
1997-2001

ACADEMIC POSITIONS:

Assistant Professor of Medicine
Duke University
1981-1989

Associate Professor of Medicine (with Tenure)
Duke University Medical Center
1989-1995

Professor of Medicine (with Tenure)
Duke University Medical Center
1995-present

Acting Chief
Division of Pulmonary and Critical Care Medicine
Duke University Medical Center
1999-2000

Chief of Clinical Services
Division of Pulmonary and Critical Care Medicine
Duke University Medical Center
2000-present

MILITARY: Research Medical Officer & Instructor in Aviation Medicine
Aviation Medicine (Cardiopulmonary) Division
Naval Aerospace Medical Research Laboratory
Pensacola, Florida 32508
1975-1978*

*Included six month course in Aviation Medicine with designation as a Naval Flight Surgeon in 1976.

MEMBERSHIPS/OFFICES HELD:

American College of Chest Physicians
- Fellow 1982 - present
- Program Committee 2000-present

American Physiologic Society

American Thoracic Society
- President, North Carolina Chapter 1989
- Member, Laboratory Standards Committee 1992-present
- Member, Program Committee 1997

American Association for Respiratory Care
- Fellow 1996 - present

- Board of Medical Advisors 1986-1991, Chairman 1990

American Lung Association
- President, Research Triangle Region 1988
- Chairman, Medical Education and Research Committee 1990-present
- Board of Directors, North Carolina Affiliate 1995 - present
- President, North Carolina Affiliate 1999-2001

American Heart Association
- Chairman, Emergency Cardiac Care Committee 1989-90
- Advanced Life Support Affiliate Faculty

Society for Critical Care Medicine

National Association of Medical Directors of Respiratory Care
- Board of Directors 1991-present
- Secretary 1995-1996, Treasurer 1997-1999, President-elect 1999-2001
- President 2001- 2002

Allergy and Asthma Network
- Board of Directors 1996 –present

American Association of Cardiovascular and Pulmonary Rehabilitation
- Fellow 1999 - present
- Board of Directors 1999-2001

BOARD CERTIFICATION: Internal Medicine 1975
Pulmonary Disease 1980
Critical Care Medicine 1989,1999

MEDICAL LICENSE: North Carolina 24929

AWARDS:
Alpha Omega Alpha, 1972
Surgeon General's Award (Aviation Medicine), 1976
American Heart Association (West Florida) Silver Service Medal, 1978
Honorary Member, North Carolina Society for Respiratory Care, 1992
Michael Newhouse MD lecture, McMaster University, Hamilton, Ontario, 1992
Listed in "Best Doctors in America"
Listed in "Who's Who in the South and Southwest"
Golden Tree of Life Award - NY Society for Respiratory Care, 1995
Honorary Member - American Association for Respiratory Care, 1995
Gerald Shapiro Award - New Jersey Society for Respiratory Care, 1996
Phillip Kittredge Honors Lecture - American Association for Respiratory Care,1997
Honorary Member, Mexican Association of Critical Care Medicine, 1998
Honorary Member, Lambda Beta Society,1999
Presidents Award, Natl Assoc of Medical Directors of Resp Care, 2000
Roger Bone Memorial Lecture, Amer College of Chest Physicians, 2000
Physician of the Year (NC Society of Resp Care), 2000
Leadership Award, NC Thoracic Society, 2000

Society of Critical Care Medicine Presidential Citation, 2000
Forrest Bird Scientific Achievement Award - American Association for Respiratory Care, 2001
Kenneth Moser Memorial Lecture, Univ Calif SD, 2002
Listed in "Best Doctors 2004" – Business North Carolina
Certificate of Appreciation – Duke University PA Program – 2004
Presidents Award – North Carolina Society of Cardiovascular and Pulmonary Rehabilitation - 2004

EDITORSHIPS:

Editorial Board, Respiratory Care, 1986- (Chairman 1990-1992)
Associate Editor, Respiratory Care, 2000-
Co-editor in Chief, Problems in Respiratory Care, JB Lippincott, Philadelphia, PA, 1988-1991
Medical Editor, Arkos, the Journal of Mechanical Ventilation, Bear Medical Systems, Riverside, CA, 1989
Editorial Board, Health Devices, 1992 -
Editorial Board, Critical Care Medicine, 1992 -
Scientific Editor, Critical Care Medicine, 1997 -
Co-editor in Chief, Respiratory Care Clinics of North America, WB Saunders, Philadelphia, PA, 1994 –
Editorial Board, Journal of Cardiopulmonary Rehabilitation, 2000-
Editorial Board, ACCP SEEK. 2002 –

PATENTS: US Patent 5438982. Endotracheal tube adapted for aerosol generation at distal end thereof, August 8, 1995

OTHER PROFESSIONAL ACTIVITIES:

Trustee, American Respiratory Care Foundation, 1988- (Vice Chairman 1990-)
Member, NIH Special Study Section 8 (SBIR, Cardiopulmonary).
Member, Steering Committee, NIH ARDS Network 1995 –
Member, Steering Committee, NIH National Emphysema Treatment Trial, 1998 2004
Member, North Carolina Board for Respiratory Care 2001-2003

NATIONAL/INTERNATIONAL C.M.E. COURSE DIRECTORSHIPS AND CONSENSUS CONFERENCE CHAIRS:

American Respiratory Care Foundation, Aerosol Consensus Conference, Cancun MX, 1990
Nagoya University Ventilator Design Conference, Nagoya, Japan, 1990
American Respiratory Care Foundation. Essentials of a Mechanical Ventilator Consensus Conference, Ixtapa MX, 1992

American Respiratory Care Foundation. Innovations in Mechanical Ventilation Consensus Conference, Ixtapa MX, 1995
American Respiratory Care Foundation. Non-invasive Positive Pressure Ventilation Consensus Conference, Vail CO, 1997
Duke University – American College of Chest Physicians. Mechanical Ventilation Course. 1997 (San Diego CA), 1998 Baltimore MD, 1999 (Phoenix AZ), 2000 (Buenos Aires Argentina and San Francisco CA), 2001 (Philadelphia), 2002 (San Diego)
Duke University – American College of Chest Physicians. Pulmonary Rehabilitation Course. 1998 (Durham NC), 1999 (Orlando FL), 2000 (San Diego CA)
American Respiratory Care Foundation. Aerosol Consensus Conference II. Bermuda, 1999
American College of Chest Physicians. Weaning Mechanical Ventilation - Evidence Based Panel 1999-2001.
American Respiratory Care Foundation. Tracheal Gas Insufflation. Dallas TX, 2000.
George Washington University - Center for Biomedical Communication. Critical Care Medicine Annual Review and Update. Washington DC, 2000-2004
Center for Biomedical Communication. Pulmonary Diseases for the Non-pulmonologist. New York, NY, 2001
American Thoracic Society. ATS-ERS Panel for DLCO Standardization. 2001-2004.
American College of Chest Physicians. Emerging Strategies for COPD. Orlando FL, 2001.
American Respiratory Care Foundation. Emerging Nebulizer Technologies, Montreal, 2002.
NAMDRC. Prolonged Mechanical Ventilation, Baltimore, 2004
American Respiratory Care Foundation. MDIs/DPIs – State of the Art, Los Cabos, MX, 2005.

PUBLICATIONS:

Original Scientific Articles (Peer Review)

MacIntyre, NR, Oberman A, Harlan WR, Mitchell RE, Graybiel A, Johnson E. Longevity in military pilots: 37-year follow-up of the U.S. Navy's "1000 Aviators". Aviat. Space and Environ. Med. 1978; 49:1120-1122.

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Ramage JE, Coleman RE, MacIntyre NR. Rest and exercise cardiac output and diffusing capacity assessed by a single slow exhalation of methane, acetylene, and carbon monoxide. Chest 1987; 92:44-50.

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MacIntyre NR, Leatherman NE. Mechanical loads on the ventilatory muscles: a theoretical analysis. Am. Rev. Resp. Dis. 1989; 139:968-973.

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Emery CF, Leatherman NE, Burker EJ, MacIntyre NR. Psychological outcomes of a pulmonary rehabilitation program. Chest 1991; 100:613-617.

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MacIntyre NR, Gropper C, Westfall T. Combining pressure limiting and volume cycling features in an interactive mechanical breath. Crit. Care Med. 1994; 22:353-357.

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National Emphysema Treatment Trial Steering Committee (MacIntyre, NR member). Rationale and design of the National Emphysema Treatment Trial. Chest 1999; 116: 1750-1761 and J Thor Cardiovasc Surg 1999; 118: 518-528.

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